

### REMARKS

This communication responds to the Office Action of August 21, 2007, which was made final, and in which claims 3, 5, 8, 10, 13, 14, 21 53 and 54 were rejected. Claims 9, 12, 15, 17, 18, 28-32, 34, 36 and 38-52 were withdrawn.

By this response, claims 8, 20 and 33 are amended. Claims 9, 12, 15, 17, 18, 28-32, 34, 36, 38-53 and 55 are canceled, without prejudice. Therefore, claims 3, 5, 8, 10-11, 13-14, 19-21, 33, 37, 54 and 56 are pending. No new matter has been added.

Reconsideration and allowance are requested.

#### Rejection Under 35 U.S.C. §§ 102 and 103

(1) Claims 3, 5, 8, 10, 13, 14, 21 53 and 54 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bley et al. (U.S. Patent 5,762,630).

(2) Claims 33, 37, 55 and 56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Iwatschenko (U.S. Patent 4,306,563) in view of Bader et al. (U.S. Patent 4,835,248).

(3) Claims 3, 5, 8, 10, 11, 13, 14, 19-21, 53 and 54 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Iwatschenko in view of Bley.

Independent claim 8, as amended, now recites:

A cannula that exhibits a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure in the cannula, said cannula configured to have a pliability that allows it to puncture a septum and a user's body, be positionable as near as possible to a desired target location and which can be moved in any direction when inserted, said cannula formed from at least one material which increases in pliability during use, wherein, prior to application, said cannula comprises a first material of a first thermally susceptible hardness and a second material having a second hardness, wherein, the thermally susceptible hardness of said first material decreases during use, wherein, the first material is or comprises a polymer.

Independent claim 33, as amended, now recites:

A cannula that exhibits a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure in the cannula, said cannula configured to have a pliability that allows it to puncture a septum and a user's body, be positionable as near as possible to a desired target location and which can be moved in any direction when inserted, said cannula formed from at least one material that increases in pliability during use, wherein the cannula comprises a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water absorption, and a material having a second hardness.

**(1) Bley does not anticipate the present invention**

**Bley does not disclose a cannula that exhibits a selected flow cross-section as claimed.** Bley discloses stylet 113 and hub 117. Fig. 1E of Bley shows stylet having a tapered distal end relative to hub 117. The tapered end results in a build-up of pressure at the distal end relative to other portions of stylet 113, and therefore the Bley stylet and hub cannot be configured to maintain a constant hydrostatic pressure as claimed in claims 8 and 33. Note: distal end of stylet 113 is not depicted in Figs 1B-1E as stylet 113 is disposed within catheter 111, thus hiding the distal end, and determining whether a constant hydrostatic can be maintained in stylet 113 is not possible using Figs. 1B-1E.

**Even if Bley exhibits a selected flow cross-section, Bley does not disclose a cannula that punctures a septum and a user's body as claimed.** The stylet 113 and hub 117 in Bley in Figs. 1B-1E is introduced into a patient's vessel 101 after needle 109 pierces skin 100 and the introducer 103 is positioned in the skin. "A needle 109 is used to make the initial cut through the skin 100 as shown in Fig. 1A. Once the needle 109, the introducer 103 and its sheath 107 are in the patient's vessel 101, the needle is removed and the introducer remains." Bley, col. 3, lines 40-45. Subsequently, stylet 113 and catheter 111 are provided in introducer 103 (see Figs. 1B-E). Thus, Bley does not disclose that stylet 113 is configured to puncture a septum and a user's body as claimed in claims 8 and 33.

**(2) Iwatschenko in view of Bader does not render the invention obvious**

**Iwatschenko does not disclose a water-absorbing material based on a polyamide as claimed, and the Office Action's statement to this effect at page 3 is correct.** In fact, Iwatschenko discloses a catheter made of a high-molecular material with an external stiffening coating that is soluble in body fluids. (*Id.*) When slowly introduced into the body, "the

stiffening coating of the catheter dissolves in the body fluids before reaching its final position.”  
Iwatschenko, col. 2, lines 66-68.

**Combining the polyamide based coating in Bader with the water-absorbing material (8) in Iwatschenko does not result in the invention as claimed.** In Bader, the polyamide coatings “are metabolized into nontoxic, nonallergenic and nonimmunogenic compounds and are excreted.” Bader, col. 1, lines 61-64. Thus, the combination of Iwatschenko and Bader would provide a cannula made of a polyamide that would be dissolved and metabolized by the body and excreted. Dissolving a substance in fluids is not the same as a substance that absorbs water. For example, a sponge absorbs water but does not dissolve, and salt dissolves in water but does not absorb water. As a result, the combination of Iwatschenko and Bader does not teach providing a water-absorbing material based on a polyamide as provided in claim 33.

**(3) Iwatschenko in view of Bley does not render the invention obvious**

**Iwatschenko in view of Bley does not provide a cannula that exhibits a selected flow cross-section as claimed.** As discussed above, Bley does not provide a cannula that exhibits a selected flow cross-section as claimed in claim 8. The catheter in Iwatschenko at Fig. 1 depicts holes 8 that “are provided in the catheter for substance to pass into the catheter.” Iwatschenko, col. 3, lines 23-24. Iwatschenko too does not provide a cannula that “exhibits a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure in the cannula” from claim 8.

**Iwatschenko in view of Bley does not disclose a cannula that punctures a septum and a user’s body as claimed.** As discussed above, Bley does not provide a cannula that configured to puncture a septum and a user’s body. Iwatschenko at Fig. 1 depicts a catheter for introduction into body cavities, e.g., oral introduction (*see* col. 2, lines 44-45). Such a configuration does not allow the catheter to pierce a septum or skin.

The cited references do not disclose or suggest the each element of the independent claims as amended. Accordingly, reconsideration and withdrawal of the claim rejections under §§ 102 and 103 are requested.

*Dependent Claims*

Dependent claims 3, 5, 10-11, 13-14, 19-21, 37, 54 and 56 depend directly or indirectly from amended independent claims 8 and 33 and are patentable for at least the reasons set forth above, and further in view of their additional recitations.

Conclusion

This response is being submitted on or before November 21, 2007 and no additional fees should be due in connection with it. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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